

**Notic of All wability**

Application N .

10/661,580

Examiner

Brian S. Kwon

Applicant(s)

KISHIKAWA ET AL.

Art Unit

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment filed 05/19/06 and Tele. Interview on 06/05/06.
2. ☒ The allowed claim(s) is/are 5.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 10/030314.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).


\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) f each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 20060530.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_.

  
Brian Kwon  
Patent Examiner  
AU1614

## **DETAILED ACTION**

### **Examiner's Amendment**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Susan J. Mack on June 5, 2006.

The application has been amended as follows:

#### Amendment to the Specification:

The title of the invention, "Antifibrotic agent containing sphingosine 1-phosphate receptor agonist or sphingosine 1-phosphate as active ingredient", is replaced with --Use of sphingosine 1-phosphate as active ingredient for the treatment of pulmonary fibrosis--.

#### Amendment to the Claim:

Claim 5. A method for treating pulmonary fibrosis, said method comprising administering to a patient in need thereof an effective amount of an antifibrotic agent consisting of a sphingosine 1-phosphate as an active ingredient and a pharmaceutically acceptable carrier to treat pulmonary fibrosis.

### ***Reasons for Allowance***

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2. The following is an examiner's statement of reasons for allowance: US 5,712,262 (Spiegel) teaches a use of sphingosine 1-phosphate in retarding apoptosis in degenerative disease such as a ischemic stroke. US 5,627,171 (Park et al) teaches a use of sphingosine-1-phosphate/N,N,N-trimethylsphingosine composition to inhibit cell motility and cell proliferation, particularly tumor cell. US 6,098,631 (Holoshitz et al) teaches a use of inhibitor of sphingomyelin signal transduction pathway including inhibitor of sphingosine phosphate formation for the treatment of autoimmune disease, particularly rheumatoid arthritis, by inhibiting proliferation and inducing apoptosis. However, the cited reference(s) alone or in combination do/does not teach or suggest the use of said composition consisting of a sphingosine 1-phosphate and a pharmaceutical acceptable carrier in treating pulmonary fibrosis.

With respect to the term "a pharmaceutically acceptable carrier" (which was introduced by the amendment filed May 19, 2006), although there is no literal support for this terminology in the specification, the specification (page 6, line 6 thru page 7, line 27, particularly page 6, line 25 thru page 7, line 18) provides sufficient examples of pharmaceutical carriers which are suitable for the administration, for example purified water, ethanol, vegetable oil, propylene glycol, polyethylene glycol and a mixture thereof as well as microcrystalline cellulose, starch, lactose, mannitol, gelatin and etc... Thus, the examiner considers that the term "pharmaceutically acceptable carrier" finds support in the specification.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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***Conclusion***

3. Claim 5 is allowed.
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov> Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon  
Patent Examiner  
AU 1614

A handwritten signature in black ink, appearing to be 'Brian', followed by a long horizontal line extending to the right.